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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/322,352	05/28/1999	CESARE PESCHILE	9855-26U1	7870

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[REDACTED] EXAMINER

SAUNDERS, DAVID A

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1644

DATE MAILED: 12/11/2001

1d

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	322,352	
Examiner	Group Art Unit	
SAUNDERS	1644	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 2/5/01.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-11, 18-32, 39-48, 51-53, 69, 71-75 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-11, 18-32, 39-48, 51-53, 69, 71-75 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

Office Action Summary

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The claim pending and under examination are 1-11, 18-32, 39-44, 51-53, 69 and 71-75.

The amendment of 7/5/01 has entered no new matter.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following rejections of record in paper 8 have been withdrawn.

- 1) The 112 first and second paragraph rejections of claims 9, 31, 32 and 44: applicant has disclosed a commercial source of the antibody, which source has identified the antibody as "260.4". The antibody can therefore be obtained and is known particularly.
- 2) The 112 first paragraph rejection of claim 68; applicant has canceled this claim.
- 3) The 112, second paragraph rejection of claim 2 (which also would have applied to claim 19): the term "pre-embryonic hematopoietic tissue" has been deleted.
- 4) The 112, second paragraph rejection of claim 39. The amendment has changed claim dependencies.
- 5) The 103 rejections over Osawa et al. and over Kabrun et al. The examiner concurs that what is expressed on mouse cells does not necessarily predict what is expressed on human cells.

The following 112, first and second paragraph rejections have been maintained.

> Claims 25 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The terms lin- and lin+ are indefinite. See further below.

1. Claims 25 and 40-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The separation of lin- and lin+ cells has not been enabled.

Specifically, the terms lin- and lin+ mean different things to different investigators, in terms of a collection or set of one or more markers selected from a large group of such. Since the term "lin" has no common meaning, despite its common usage, the claims are indefinite and since the reader does not know which set of markers applicant intended, one would not know how to practice the claimed invention.

New 112 second paragraph rejections necessitated by applicant's amendment are stated as follows:

Claims 18-32, 39-44 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claim 18 is confusing as to whether one is isolating human progenitor cells (HPCs) or human stem cells (HSCs) also the claim is unclear as to whether HPCs are to be isolated (i.e. in two-steps) as in original claim 18 or whether there is only one isolating step, as instantly. Note dependent claims 23-32, 39-44 and 75 seem to imply that there is an intermediate step of

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isolating HPCs, before isolating KDR+ HPCs. In this regard, note that in claims 24-25, 27, 39 and 75 "the HSCs" lack antecedent basis, because claim 18 has only recited KDR+ HPCs.

➤ A new 112, first paragraph rejection is stated as follows.

Claims 23-27 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The antibody^{es} recited in claims 23-27 and 39-40 does not select for the KDR+ marker; therefore these antibodies cannot isolate HPCs that express KDR on their surface from HPCs that does not express KDR on their surface, as required by claim 18, lines 2-4.

The following prior art rejections have been maintained.

*else these
claims intended
to state how
The HPC pop
is selected?
but claim is
is that cls still
K DR+*

➤ Claims 1-3, 5, 18-19, 22-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatia et al. (ref. 14) for reasons of record.

➤ Claims 1-5, 18-19 and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutherland et al. (ref. 63) for reasons of record.

➤ Claims 18, 26, 39 and 51-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Zanjani et al. (ref. 77) for reasons of record.

➤ Claims 1-5, 18, 22-27 and 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandt et al. (ref. 17) for reasons of record.

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Applicant's arguments regarding the above cited references that the cells of the prior art have not been selected according to their expression of KDR on their surface is unconvincing. It is noted that nothing in the rejected claims positively requires one to use a reagent or antibody which specifically binds KDR. Since applicant's own specification has shown that KDR is expressed on a fraction (ca 1%) of both CD34+ and CD34- cells and has also shown that KDR is expressed on a fraction of CD34- lin - cells (ca 1%), any method that isolates such cells based upon their expression of CD34 and/or lin markers would inherently enrich the KDR+ cells from an extremely low percentage (in unfractionated hematopoietic tissue) to about 1%. This is all that is required by the claim language.

Applicant's arguments filed 7/5/01 have been considered but are unconvincing.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

✓ It has been noted that this application recites nucleic acid sequences with SEQ ID NOS (e.g. page 41). Full compliance with 37 CFR 1.821-1.825 is required. No sequence listing has been provided in Paper or CRF formats.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 a.m. to 4:45 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

Dec. 6, 2001

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644